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The Contraceptive CHOICE Project: Recruiting Women at Highest Risk for Unintended Pregnancy and Sexually Transmitted Infection

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Abstract

Background: Unintended pregnancy disproportionately affects younger, minority, and low-income women. The purpose of this analysis is to describe our recruitment strategies and to determine if targeted efforts to reach women at greatest risk for unintended pregnancy and sexually transmitted infection (STI) were successful.

Methods: The Contraceptive CHOICE Project is a prospective cohort study providing reversible contraception at no cost to 10,000 women aged 14–45 years in the St. Louis area in order to evaluate method satisfaction and continuation and to reduce unintended pregnancies in the region. We describe four strategies for effective outreach and recruitment of high-risk women, including forming strong community partnerships. We analyze the evolution of baseline demographic and behavioral characteristics over the three waves of enrollment of the first 2,500 participants in order to assess whether our outreach efforts were successful.

Results: Overall, >60% of participants were aged ≤ 25 years. There was a significant increase in the percentage of minority participants enrolled throughout the first 2,500 subjects ($p < 0.001$). The number of women who reported trouble paying for basic necessities significantly increased over the three waves ($p = 0.025$). Throughout the three waves of enrollment, there was a significant increase in the number of women who tested positive for an STI at baseline ($p < 0.001$).

Conclusions: A multiple method approach with collaboration of key community partners led to successful recruitment of hard to reach populations at high risk for unintended pregnancy and STI.

Introduction

ALL WOMEN SHOULD HAVE THE OPPORTUNITY to make decisions about their own reproductive health and if and when they desire pregnancy. Of the 6.4 million pregnancies that occur in the United States each year, however, nearly half (49%) are unintended.¹ Unintended pregnancy in the United States affects certain subgroups of the population at much higher rates; these groups include young women (aged 18–25 years), those with lower-income status and lower education level (did not complete high school), and minority race.^{1–4}

In nearly half (48%) of all unintended pregnancies, contraceptives were used during the month of conception.¹ Contraceptive failure is most often a result of inconsistent or incorrect use.⁵ Women of low income, minority racial or ethnic groups, or younger age are more likely to experience elevated contraceptive failure rates.³ Long-acting reversible

methods of contraception (LARC), which include intrauterine devices (IUDs) and the subdermal implant, have been proven to be the most effective methods of reversible contraception, with failure rates of <1% in the first year of use.⁶ These methods do not require routine compliance, such as daily or weekly regimens. There is no significant difference in the effectiveness of the long-acting methods across racial or ethnic groups.³

Despite their known safety and effectiveness, LARC use is much lower in the United States compared with the rest of the world.⁷ One reason for this is that misconceptions and myths about IUDs remain among women and healthcare providers; as a result, they are often not offered to women as first-line options or to women who are at higher risk for infection and unintended pregnancy.^{8–10} LARC methods are also associated with a higher upfront cost to both patient and provider despite their cost-effectiveness in the long term.¹¹

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Previous studies have reported the challenges that occur when identifying, enrolling, and retaining high-risk or hard-to-reach populations in research. These challenges include a generalized distrust among minorities of medical research, a lack of clinical trials at facilities where minorities seek medical care, ineffective communication by research staff, complicated record-keeping requirements, a lack of incentives, and lack of transportation or child care.¹² The reasons cited more often by minority subjects who withdrew from a multicenter research trial were lack of time, negative side effects, and dissatisfaction with the overall research process.^{12,13}

The Contraceptive CHOICE Project (CHOICE) was developed to (1) increase awareness and acceptance of LARC, (2) remove the knowledge and financial barriers to the most effective methods of birth control, and (3) decrease the rate of unintended pregnancy at the population level among women in the St. Louis area. During the development phase of the study, we identified and implemented specific recruitment strategies to increase enrollment among women at highest risk for unintended pregnancy and sexually transmitted infection (STI). This report describes the evolution of demographic and behavioral characteristics of the first 2,500 women enrolled in CHOICE during a 17-month enrollment period. Our objective is to demonstrate that the expanded efforts to reach high-risk women were successful in improving recruitment and enrollment of these women into the study.

Materials and Methods

The Contraceptive CHOICE Project (CHOICE) methods have been described previously.¹⁴ In summary, CHOICE is a prospective cohort study planning to enroll 10,000 women aged 14–45 years in the St. Louis area. Eligible women have been sexually active with a male partner in the past 6 months or anticipate sexual activity in the next 6 months, have not had a tubal ligation or hysterectomy, do not desire pregnancy in the next year, and are interested in starting a new reversible contraceptive method. Each participant is provided reversible contraceptive method(s) of her choice at no cost for 3 years. At enrollment, each participant receives contraceptive counseling, STI (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, syphilis, and HIV) screening, and a staff-administered standardized survey instrument. After her in-person baseline enrollment session, the participant is interviewed by telephone seven times (3 months, 6 months, and every 6 months to 3 years) to measure method continuation, satisfaction, and pregnancy occurrence. The Washington University in St. Louis Human Research Protection Office approved the protocol before participant recruitment.

During the development phase of the study, we identified four strategies to ensure the successful recruitment of high-risk women, as identified by age ≤ 25 , minority racial or ethnic group, low income, and a history of or current STI (Table 1). First, we identified community partners that shared similar goals and objectives. The community partners included federally qualified health centers, local family planning clinics, and clinics providing abortion services. We identified areas of our metropolitan area with high STI prevalence and targeted clinics in those neighborhoods as well as clinics in any location providing abortion services. Once a community site was willing to partner with us, we confirmed that the clinic serves

our target population by requesting data on the range of patient age, race, income, and the clinic's service region.

We established mutually beneficial relationships for both the community sites and CHOICE to ensure the sustainability of the relationship over time. CHOICE and the community partners shared organizational priorities to identify recruitment challenges, competing needs, and financial considerations and possible solutions. For example, together we recognized the importance for research staff to recruit at community clinics to reach women who did not or would not seek care at a university-affiliated clinic; in turn, we acknowledged the value of ensuring that study participants continued to receive medical services within the community partner clinics. Similarly, by establishing a trusted relationship with community-based partners, the study referred women recruited at the university-affiliated clinic to the community clinics for future medical services. Through this mutually supportive system, we were able to recruit the target population from sites where women actually seek reproductive health services and ensure that we promoted continued care within the community clinics. Staff at the community clinics became our biggest proponent and promoted the study to their patient population.

Second, we recognized our inability to recruit at all area clinics and reproductive health providers because of staffing limitations. In response, we initiated conversations with private providers who expressed an interest in the study and encouraged referral of their patients to the study to obtain contraception. We provided posters and pamphlets to have on display and available in their clinics. We again established a system wherein private patients were referred to CHOICE for enrollment and referred back to the private physician for clinical care, contraceptive method insertion (if applicable), and management. We believed that a referral by a trusted medical provider would provide the patient with an important level of confidence and legitimacy so that she would contact the study for more information and subsequent participation.

Third, we established a standardized recruitment monitoring process to regularly evaluate recruitment goals and outcomes. To meet our target of 10,000 women enrolled in 4 years, our enrollment goal was approximately 200 women each month. For each recruitment location, we generated a database that was updated daily to enumerate the number of women approached and the number of women who enrolled by age and race. We also reported reasons for ineligibility and reasons for not enrolling in the study. We documented recruitment days, time spent during each recruitment event, and unusual circumstances that may have influenced recruitment. Initially, we monitored recruitment outcomes on a daily basis to identify successes, challenges, and new recruitment strategies. Over time, we transitioned to monitoring recruitment goals and outcomes on a weekly basis to account for daily fluctuations.

Finally, we did not underestimate the magnitude of a positive participant experience and the value of word-of-mouth advertising. The research staff was trained and repeatedly reminded to prioritize each woman's experience to ensure her level of comfort, her questions were answered, her confidentiality was protected, and our appreciation of her participation was verbalized. During the course of the enrollment session, we offer participants small cards with CHOICE contact information to pass along to friends or

TABLE 1. RECRUITMENT STRATEGIES USED TO ENROLL WOMEN AT RISK OF UNINTENDED PREGNANCY INTO CONTRACEPTIVE CHOICE PROJECT

<p>Form mutually beneficial relationships with community partners serving target population</p> <p>Identify community partners</p> <ul style="list-style-type: none"> ▪ Federally qualified health centers (Title X) family planning clinics ▪ Located in high-prevalence STI areas ▪ Provide abortion services <p>Confirm sites serve target population through existing data sources</p> <p>Identify organizational strengths and weaknesses</p> <ul style="list-style-type: none"> ▪ Priorities ▪ Challenges ▪ Financial constraints ▪ Referral location for women who don't have a current provider <p>Develop and formalize mutually agreed upon protocols and remuneration</p> <p>Standardize recruitment monitoring process to evaluate recruitment outcomes</p> <p>Establish recruitment goals</p> <ul style="list-style-type: none"> ▪ Weekly to account for daily fluctuations <p>Create database to collect key recruitment indices</p> <ul style="list-style-type: none"> ▪ Age ▪ Race ▪ Recruitment location ▪ Recruitment time ▪ Reasons for ineligibility ▪ Reasons for not enrolling <p>Review recruitment indices on a regular basis to identify</p> <ul style="list-style-type: none"> ▪ Successes ▪ Challenges ▪ New strategies <p>Implement and monitor new strategies</p>	<p>Expand beyond designated recruitment sites</p> <p>Identify private providers willing to refer their patients to CHOICE</p> <p>Demonstrate willingness to refer patient back to provider for method insertion to ensure continuity of care</p> <p>Consistently provide study pamphlets and posters to private provider network</p> <p>Refer patients back to private providers for ongoing management</p> <p>Create a positive experience for each participant and facilitate additional enrollments within her social network</p> <p>Ensure staff is trained to provide positive experience</p> <p>Prioritize each participant's CHOICE interaction</p> <ul style="list-style-type: none"> ▪ Ensure she is comfortable ▪ Encourage and answer her questions ▪ Demonstrate that we will protect her confidentiality ▪ Thank her for her participation <p>Distribute Project contact information cards to participants to give to her friends and family</p>
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STI, sexually transmitted infection.

family members who might be interested in CHOICE. This strategy was implemented to encourage women who are trusted by friends or family members to speak positively about their CHOICE experience and possibly facilitate additional enrollments within their peer or social networks.

In this report, we analyze the effectiveness of our recruitment strategies and whether we have successfully recruited women at high risk for unintended pregnancy and STI over time. We compare demographic and behavioral characteristics among the first three waves of women enrolled in CHOICE. Specifically, of the first 2,500 women enrolled, we compared waves of 500, 1,000, and 1,000 women enrolled. We examine several risk factors for unintended pregnancy including age, race, financial status, and STI at the time of enrollment. Statistical analyses were conducted using SAS Software (version 9.1., SAS Institute, Cary, NC). The chi-square test was used for categorical variables, and a *t* test or analysis of variance (ANOVA) was used for continuous variables.

Results

The first 2,500 subjects of CHOICE were enrolled over a 17-month period, from August 2007 to December 2008. During that time, 4,197 women were screened and 3,524 (84%) were eligible. The first 500 women (wave 1) were enrolled in months 1–6 of the study; these participants were recruited at the

university-affiliated clinic and one clinic providing abortion services. Participants 501–1,500 (wave 2) were enrolled in months 7–12; one clinic providing abortion services and two family planning clinics were added as recruitment sites during this wave. Participants 1,501–2,500 (wave 3) were enrolled in months 13–17, and four additional family planning clinics as well as one no-cost teen clinic were added as recruitment sites. Overall, 26% of the participants were recruited at a community-based partner clinic: 18% at the abortion facilities and 8% at the federally qualified health centers or family planning clinics (Table 2). There was not a significant increase in recruitment at community-based clinics between waves 1 and 2 ($p = 0.315$). However, when numerous additional community clinics were added in wave 3, there was a significant increase between waves 2 and 3 in the number of participants enrolled outside of the university-affiliated clinic ($p < 0.001$).

We observed changes in the demographic and economic profiles among the three comparison groups. The number of participants who identified themselves as black significantly increased early in the study, from 33% in wave 1 to 47% in wave 2 ($p < 0.001$). This early increase in minority race was stable between waves 2 and 3 ($p = 0.928$). The age of the participants remained consistent over time. The average age of participants was 25 years, ranging from 14 to 45 years. Overall, >60% of participants were aged ≤ 25 , and 99 participants (6%) were minors <18 years (Table 2).

TABLE 2. EVOLUTION OF DEMOGRAPHIC AND BEHAVIORAL CHARACTERISTICS THROUGHOUT FIRST THREE WAVES OF ENROLLMENT IN CONTRACEPTIVE CHOICE PROJECT, N=2,500

	Total		Wave 1	Wave 2	Wave 3		Wave	Wave	Wave
	n	%	1st 500	2nd 1000	3rd 1000	p value	1 vs. 2	2 vs. 3	1 vs. 3
			%	%	%		p value	p value	p value
Recruitment clinic						<0.001	0.315	<0.001	<0.001
University-affiliated	1845	73.8	78.6	75.1	70.1				
Abortion	444	17.8	17.0	19.5	16.4				
Family planning/community health	211	8.4	4.4	5.4	13.5				
Race						<0.001	<0.001	0.928	<0.001
Black	1086	43.7	32.5	46.7	46.2				
White	1209	48.7	60.6	45.6	45.7				
Other	190	7.6	6.9	7.6	8.1				
Hispanic						0.360	0.461	0.408	0.167
Yes	114	4.6	3.6	4.4	5.2				
Age						0.742	0.608	0.620	0.663
<18	99	4.0	3.8	3.5	4.5				
18–20	426	17.0	15.8	18.0	16.7				
21–25	1053	42.1	44.6	41.6	41.4				
>25	922	36.9	35.8	36.9	37.4				
Trouble paying						0.025	0.949	0.014	0.040
Yes	968	39.0	36.7	36.9	42.3				
Receive public assistance						0.167	0.104	0.811	0.069
Yes	719	28.9	25.5	29.5	29.9				
Trouble paying or receiving assistance						0.046	0.254	0.121	0.016
Yes	1281	51.7	47.8	50.9	54.4				
Lifetime sex partners						0.233	0.079	0.583	0.268
0–1	364	14.6	13.8	14.0	15.5				
2–4	671	26.8	28.6	26.1	26.7				
5–9	849	34.0	30.0	36.3	33.6				
10+	616	24.6	27.6	23.6	24.2				
History of abortion						0.001	0.971	0.001	0.007
Yes	1128	45.1	48.0	48.1	40.7				
Any STI diagnosis in lifetime ^a						0.144	0.733	0.104	0.097
Yes	702	28.4	26.4	27.2	30.6				
Any STI at baseline ^b						<0.001	0.110	0.006	<0.001
Yes	120	4.8	2.4	4.0	6.8				
Parity						0.779	0.546	0.661	0.783
0	1236	49.4	50.4	48.5	49.9				
1	585	23.4	24.6	23.0	23.2				
2	429	17.2	16.0	18.5	16.4				
3+	250	10.0	9.0	10.0	10.5				
Reached desired parity						0.899	0.707	0.927	0.652
Yes	953	38.1	39.0	38.0	37.8				

^a*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, syphilis, herpes, or HIV.

^b*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*.

The number of participants who reported they had trouble paying for transportation, housing, medical expenses, or food in the past 12 months increased significantly from 37% in wave 2 to 42% in wave 3 ($p=0.014$). The number of women currently receiving food stamps, Women, Infants, and Children (WIC), welfare, or unemployment benefits also increased over time, although not significantly from wave 1 to wave 3 ($p=0.069$). Combined, the number of participants who reported difficulty paying for basic necessities or currently receiving public assistance increased from 48% in wave 1 to 54% in wave 3 ($p=0.016$).

The number of reported lifetime sexual partners remained consistent across the three waves in the first 2,500 participants. Overall, 59% of participants reported ≥ 5 lifetime sexual partners. Forty-five percent of participants reported a history of abortion. The proportion of participants with a self-reported

history of STI diagnosis (including *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis*, syphilis, herpes, or HIV) was 28% (Table 2). Although we did not observe a significant increase in self-reported history of STI over time, we did observe a statistically significant increase in the number of participants who tested positive for an STI (*C. trachomatis*, *N. gonorrhoeae*, or *T. vaginalis*) at their baseline enrollment session, from 2% in wave 1 to 7% in wave 3 ($p<0.001$). There is no difference among the waves in terms of parity or the number of participants who have already reached their desired parity (Table 2).

Discussion

Significant disparities exist in the sexual and reproductive health of women in the United States. CHOICE has focused its

recruitment efforts to increase participation among women at high risk of unintended pregnancy, including women of low income, younger age, black race, and those who engage in high-risk sexual behaviors.^{2-5,15} We believe our efforts to reach high-risk women have been successful. Our success has been accomplished through expansion of recruitment sites to include community health and family planning clinics located throughout the recruitment catchment area, especially in low-income neighborhoods. CHOICE has forged strong relationships with healthcare providers and staff at the community-based clinics, who play an important role in introducing CHOICE to their patient population. Furthermore, existing participants through word-of-mouth referred other women to CHOICE. Planned efforts to further increase awareness of the project include advertisements in city newspapers and on local radio stations as well as on public transportation buses and trains.

During the first 17 months of recruitment, the demographic and sexual risk characteristics of the participants changed over time. The number of black participants significantly increased, and nearly half of our participants are from a minority racial or ethnic group. The large proportion of minority women enrolled in CHOICE accurately reflects the racial distribution of the recruitment catchment area of St. Louis city, where 49% of the residents are black, 47% are white, and 3% are of Hispanic ethnicity.¹⁶ We also observed a significant increase in the number of participants reporting difficulty paying for basic necessities or receiving public assistance. Finally, the number of participants who tested positive for an STI at baseline enrollment significantly increased over time. These three indicators of high risk suggest that one or more of the four strategies implemented to reach high-risk women has been effective in recruiting our target population. However, because the recruitment strategies were not staged but implemented in overlapping time intervals early in the study, the effectiveness of each strategy cannot be evaluated individually.

Although we enrolled 99 women <18 years of age, we did not observe a significant increase in the number of teen participants during this time period, suggesting that our strategies were not focused on the youngest women at risk of pregnancy. This may be because parental consent is required for minor participation in the study. Alternatively, teens may not seek care at the community clinics where we offer participation. We initiated recruitment at a teen clinic that provides no-cost healthcare services in the last month of the third wave and expect to see increased enrollment from that site in future recruitment waves. Because adolescents are a target population for the study, measures have been undertaken to identify additional teen-specific clinics in the community.

The disparities seen in rates of unintended pregnancy are mirrored in rates of abortion. More than half (56%) of women obtaining an abortion are in their 20s, and women aged 20–24 have a higher abortion rate than any other age group. Women with incomes below 200% of poverty comprise 30% of all women of reproductive age but accounted for 57% of all women having abortions in 2000. Additionally, the abortion rate in white women (13/1,000) is the lowest of any racial group, but that of black women (49/1,000) is the highest.² CHOICE's partnership with clinics providing abortion services provides women with an opportunity for contraception who may not otherwise seek or have access to routine reproductive healthcare or affordable contraception at the time

of an abortion procedure. Furthermore, participants are able to obtain their chosen method immediately at the time of their procedure, thus eliminating the need to return at a later date to obtain contraception.

Substantial health disparities also exist in the rates of STI in the United States; the rate of infection with *N. gonorrhoeae* is 19 times higher in black women than white women, and the rate of infection with *C. trachomatis* is more than 8 times higher in black women than white women.^{17,18} Young age is also a risk factor for STI, with the highest rates in 15–19 and 20–24 year olds.^{18,19} Additional STI risk factors include low socioeconomic status, limited access to healthcare, incarceration, and involvement in highly infected sexual networks.²⁰⁻²² Within this analysis, we are able to demonstrate that efforts to enroll women at risk of unintended pregnancy also effectively enrolled women at high risk of STI, as shown by increased rates of STI at the time of enrollment. Health disparities occur in behaviors that overlap, including STI and unintended pregnancy, and should be considered in tandem within high-risk populations.²³

Women of low income, those of minority racial or ethnic groups, and younger women are more likely to experience elevated contraceptive failure rates.^{3,5} The average failure rate across all contraceptive methods as a group in the first year of use is >10% for all women except those aged 30–44, married, or in the highest income status category. In the second year of method use, the failure rate remains >10% only for women with an income less than 250% of poverty and black women.³ These disparities in failure rates likely exist for several reasons. Contraceptive users in these groups may have less education about consistent and correct method use. Additionally, these women have limited access to the resources to obtain contraceptives routinely and at an affordable price.³ In order to lessen these disparities, CHOICE is removing financial barriers, providing straightforward access to all contraceptive methods, including refillable methods, and providing education on proper method use.

Given that contraceptive failure is more likely with the refillable methods, a forgettable method that is not user dependent and does not need to be obtained on a routine basis is preferable. For this reason, CHOICE provides a brief educational message on the safety and effectiveness of long-acting reversible methods to all participants. The goal is to dispel widespread myths and misinformation about LARC.^{24,25} The long-acting reversible methods may be even more preferable for those high-risk women with limited access to contraception, an unstable income, or a lack of knowledge on appropriate method use.

Conclusions

The Contraceptive CHOICE Project aims to have a population-level impact on the rate of unintended pregnancy in the St. Louis area by providing reversible contraception of the woman's choice at no cost. In order to truly reduce unintended pregnancy at a population level, the project must reach the women at highest risk for unintended pregnancy and provide the most effective methods of contraception. We believe that through a multiple method approach, with collaboration of key community partners, we have been increasingly effective at reaching high-risk women during the time period wherein the first 2,500 participants enrolled in the study. Future efforts will identify additional strategies to

increase recruitment of teens and to maintain our recruitment of minority and lower-income women.

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Disclosure Statement

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